DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN - 1 2001

Mr. Michael Turanchik
Director
Research & Development
Medtox Diagnostics, Inc
1238 Anthony Road
Burlington, NC 27215

Re: 510(k) Number: K010226
Trade/Device Name: Verdict® -II Methamphetamine
Regulation Number: 862.3610
Regulatory Class: II
Product Code: DJC
Dated: January 22, 2001
Received: January 24, 2001

Dear Mr. Turanchik

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

EXHIBIT III VERDICT®-II METHAMPHETAMINE 510(k) Submission

INDICATIONS FOR USE FORM

510(k) Number (if known): K010226

Device Name: VERDICT®-II METHAMPHETAMINE

Indications for Use:
VERDICT®-II METHAMPHETAMINE is a one-step immunochromatographic test for the rapid, qualitative detection of methamphetamine (MAMP), 3,4 methylenedioxymethyl amphetamine (MDMA) and their metabolites in human urine. It is not for over-the-counter sale. The test detects the major urinary metabolites of the two drugs at these cut-off concentrations:

MAMP	Methamphetamine	1000 ng/mL
MDMA	3,4 methylenedioxymethyl amphetamine	1500 ng/mL

VERDICT®-II METHAMPHETAMINE PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATE CHEMICAL METHOD MUST BE USED IN ORDER TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GAS CHROMATOGRAPHY/ MASS SPECTROMETRY (GC/MS) IS THE PREFERRED CONFIRMATORY METHOD FOR METHAMPHETAMINE AND 3,4 METHYLENEDIOXMETHYL AMPHETAMINE. CLINICAL CONSIDERATION AND PROFESSIONAL JUDGMENT SHOULD BE APPLIED TO ANY DRUG OF ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE OBTAINED.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Fred Lacy
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K010226

Prescription Use ✓ or Over-The-Counter Use _____
(Per 21 CFR 801.109)